IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	C.A. No. 05-340 (SLR) (Consolidated)
THIS DOCUMENT RELATES TO: ALL ACTIONS	**REDACTED PUBLIC INSPECTION VERSION**
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	C.A. No. 05-360 (SLR) (Consolidated)
THIS DOCUMENT RELATES TO: ALL ACTIONS	

PURCHASER PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON THE "SHAM LITIGATION" AND WALKER PROCESS CLAIMS

Dated June 2, 2008

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TABLE OF AUTHORITIES

Rather than unnecessarily encumber the Court with duplicative briefing, Direct Purchaser Plaintiffs ("DPPs"), End Payor Plaintiffs ("EPPs") and Pacificare Health Systems, Inc. (collectively, "Purchaser Plaintiffs") hereby incorporate by reference the arguments and authorities of Teva Pharmaceuticals, Inc. ("Teva") and Impax Laboratories, Inc. ("Impax") in their concurrently-filed briefs addressing the sham litigation and *Walker Process* issues. However, Purchaser Plaintiffs write separately to address briefly several arguments and issues regarding the lawsuits filed by Abbott Laboratories and Fournier Laboratoires S.A. ("Defendants") relating to Teva's capsule formulation that are not covered in those briefs.[1]

I. INTRODUCTION AND SUMMARY OF THE ARGUMENT

The sole patent asserted by Defendants against Teva in the Capsule Litigation was United States Patent No. 4,895,726 (the "Curtet Patent"), which is attached as Chorush Declaration ("Decl.") Exhibit ("Exh.") A. The Curtet Patent applicants did not invent—and do not claim to have invented—fenofibrate, the active pharmaceutical agent ("API") in Tricor. Nor did the Curtet Patent applicants invent the use of micronization[2] or surfactants[3] to increase the dissolution rate of poorly water-soluble drug substances such

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[1] The cases against Teva were styled *Abbott Labs v. Novopharm Ltd.*, Civ. Nos. 00C2141, 00C5094, and 01C1914 (N.D. Ill.). Defendants originally filed suit against Novopharm Limited ("Novopharm"). However, Novopharm was since acquired by Teva and the two entities are referred to collectively herein as "Teva."

[2] The term "micronization" was well known in the late 1980s and early 1990s and meant the reduction of a solid particle's size into the micron size range using physical forces such as milling or grinding. Elder Decl. Exh. B ¶ 15. Nalven Decl. Exh. B (Kaplan Reply report) ¶ 13 [redacted]

[3] The term "surfactant" was also well known in the late 1980s and early 1990s and meant a surface-active agent capable of reducing surface tension. Elder Decl. Exh. B ¶ 17.

as fenofibrate. Elder Decl. Exh. B ¶ 13.[4] Instead, the Curtet Patent asserts as a narrow invention[5] the discovery of improved bioavailability accomplished through "co-micronization of fenofibrate and a solid surfactant," which the patent defines as "the micronization of an intimate mixture of fenofibrate and a solid surfactant." Chorush Decl. Exh. A at 1:35-43. Each of the claims of the Curtet Patent requires "co-micronization" (or that the product be "co-micronized"), as well as a "solid surfactant."[6] *Id.* at 5:6-6:30.

In their litigation against Teva's proposed capsules, Defendants took three unreasonable positions, each of which independently renders the Capsule Litigation objectively baseless. First, although Defendants narrowly defined the term "co-micronization" in the Curtet Patent, they unreasonably ignored that definition during litigation. Defendants could not have realistically expected success on this issue. Second, Defendants' infringement theory under even their own proposed broader construction for "co-micronization" was preposterous because it encompassed formulations that the Curtet Patent describes as <u>not</u> co-micronized. This is—on its face—unreasonable.[7]

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[4] Indeed, the Curtet Patent acknowledges that those techniques were "known." Chorush Decl. Exh. A at 1:28-34.

[5] Fournier recognized this. [redacted] Chorush Decl. Exh. B.

[6] The two independent claims in the Curtet Patent—namely, claims 1 and 10—require "a co-micronized mixture of particles of fenofibrate and a solid surfactant" and "co-micronization of the fenofibrate and a solid surfactant," respectively. Elder Decl. Exh. B ¶ 11. There is no substantive difference in meaning between "co-micronized" and "co-micronization" (other than as different parts of speech). Chorush Decl. Exh. C (Goldberg Dep.) at 99:19-100:13.

[7] An infringement analysis is a two-step process involving first claim construction and second a comparison between the properly construed claims and the accused product.

Finally, it is undisputed that the Teva's process employed a surfactant dissolved in a liquid, which even Defendants' expert concedes is in the liquid phase rather than the solid phase. Consequently, Teva did not employ a "solid surfactant" as required by the Curtet Patent claims. As explained further below, genuine issues of fact preclude summary judgment on each of these issues.

II. ARGUMENT

A. Defendants Could Not Reasonably Believe They Were Entitled to the Ordinary Meaning of "Co-Micronization."

The Curtet Patent claim construction issue relating to "co-micronization" is straightforward—namely, whether the required "co-micronization" of fenofibrate and a solid surfactant must be performed in the absence of other materials. In the Capsule Litigation, Teva (as well as Impax) argued "yes," while Defendants argued "no." There is no question today who was right and who was wrong. Each of the five judges who has addressed this issue has rejected Defendants' argument and held that the co-micronization process must exclude materials other than the fenofibrate and solid surfactant.[8] Indeed, a unanimous panel of the Federal Circuit found it not just clear, but "abundantly clear," that Defendants were wrong. *Abbott Laboratories*, 323 F.3d at 1330.

The Curtet Patent applicants availed themselves of their well-settled right to act as lexicographers "by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." *Jack*

Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). Here Defendants advanced unreasonable positions with respect to both steps.

[8] *Abbott Laboratories v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003); *Abbott Laboratories v. Novopharm Ltd.*, Civ. No. 00C2141, 00C5094 and 01C1914, 2002 WL 433584, *7 (N.D. Ill. March 20, 2002); *Abbott Laboratories v. Impax Pharmaceuticals, Inc.*, Civ. No. 00C5092, 00C7865 and 01C1648, 2003 WL 1563426, *5 (N.D. Ill. March 26, 2003).

Guttman, Inc. v. Kopykake Enterprises, Inc., 302 F.3d 1352, 1360 (Fed. Cir. 2002) (setting forth "black letter law"). Specifically, they wrote in the Patent:

> [T]he co-micronization of fenofibrate and a solid surfactant (***i.e.* the micronization of an intimate mixture of fenofibrate and a solid surfactant**) makes it possible to improve the bioavailability of the fenofibrate to a significantly greater extent than that which would be achieved either . . . by intimately mixing the separately micronized fenofibrate and surfactant.

Chorush Decl. Exh. A at 1:35-43 (emphasis added). The Latin abbreviation "i.e." stands for "id est," which in English means "it is." Chorush Decl. Exh. D (Colaianni Report) at 14. The above parenthetical indisputably refers back to the phrase "co-micronization of fenofibrate and a solid surfactant," and thus defines explicitly what "it is."

Although Defendants contend that this act of lexicography is not sufficiently clear to trump the "ordinary" meaning,[9] [redacted] the Curtet Patent applicants defined the term "co-micronization" as a "micronization of an intimate mixture." Chorush Decl. Exh. E (Goldberg Report) at 6 (emphasis added). [redacted] Elder Decl. Exh. B ¶ 19; Nalven Decl. Exh. A (Kaplan Report) ¶¶ 24 & 27 and B (Kaplan Reply Report) ¶¶ 15-16. So too did a

[9] Although Defendants cite *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002) for the proposition that they were entitled to the "ordinary meaning" of "co-micronization," that case did not change the long-standing rule that patent applicants could act as lexicographers. To the contrary, it reaffirmed it: "[T]he presumption in favor of a dictionary definition will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning." *Id.* at 1204. Under those circumstances, the dictionary definition "must be rejected." *Id.* Defendants have cited no legal authority justifying them in narrowly defining "co-micronization" in the patent application to evade meaningful review at the Patent and Trademark Office only to advance a much broader, more inclusive construction against the public in litigation.

unanimous Federal Circuit panel. *Abbott Laboratories*, 323 F.3d at 1330 (finding Defendants' act of lexicography to be "abundantly clear").[10]

The Curtet Patent's requirement that an "intimate" mixture of fenofibrate and solid surfactant be micronized is dispositive of the key claim construction issue—namely, whether materials other than fenofibrate and solid surfactant can be present during the co-micronization. [redacted] Elder Decl. Exh. B ¶ 23. Dr. Elder's interpretation accords with the specification and prosecution history of the Curtet Patent. [redacted] the text in the Curtet Patent contemplates adding other materials after the fenofibrate and solid surfactant have been micronized. Chorush Decl. Exh. C (Goldberg Dep.) at 186:25-188:8; *see also* Nalven Decl. Exh. A (Kaplan Report) ¶ 27. Likewise, [redacted] each of the preparative examples in the Curtet patent involve co-micronization in the absence of excipients. Chorush Decl. Exh. C (Goldberg Dep.) at 190:14-24.[11] This was not a case (as Defendants contend) of reading

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[10] [redacted]

[11] Defendants have never articulated any reasonable meaning for "intimate" that would not require the exclusion of materials other than fenofibrate and solid surfactant. Although Defendants argue that the term "intimate" could mean "that the ingredients are well-mixed such that they are in close proximity" (Defendants' Brief at 14 n.6), [redacted] Thus, interpreting the word "intimate" in the phrase "intimate mixture" to mean "close" would render the term "intimate" meaningless surplusage. *Texas Instruments Inc. v. United States Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (rejecting a patentee's proffered claim construction because it "would render the disputed claim language mere surplusage."); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) ("All the limitations of a

limitations into the claims from the embodiments, but rather a case in which all evidence—the claims themselves, the specification definition of "co-micronization, and all of the embodiments—point unequivocally to the same conclusion.

The reexamination history of the Curtet Patent provides yet further confirmation of the narrow meaning of "co-micronization" as excluding the presence of materials other than fenofibrate and the solid surfactant from the "intimate" mixture:

> Unlike the Boullay teaching, lactose does not intervene in the co-micronization in the present invention. It [lactose] is used in the present invention . . . after the co-micronization of the fenofibrate/sodium lauryl sulfate mixture, for granulation purposes with starch. . . .

Chorush Decl. Exh. G (Reexamination Response dated April 24, 2000) at 5 (emphasis added).[12] A reasonable competitor of Defendants, after reviewing the Curtet Patent prosecution history, would necessarily conclude that the Curtet Patent claims are limited to fenofibrate formulations and methods for using them in which an exclusive mixture (*i.e.*, excluding other components) of particles of fenofibrate and solid surfactant are micronized. Elder Decl. Exh. B ¶ 24.

Given the proper construction of "co-micronization," Defendants had no reasonable infringement theory. Indeed, despite several years in which to think

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claim must be considered meaningful."). Interpreting "intimate" to mean "well-mixed" also makes no sense. [redacted] Elder Decl. Exh. B ¶ 23; Chorush Decl. Exh. C (Goldberg Dep.) at 177:17-24; Nalven Decl. Exh. B (Kaplan Reply Report) ¶ 16. The common parlance meaning for "intimate" is not "well mixed."

[12] [redacted], the PTO specifically informed Defendants that the Reexamination Response would "remain in the record," where the public could access it. Chorush Decl. Exh. H (PTO Reexamination Correspondence). Defendants never moved to expunge the Reexamination Response from the publicly-accessible record and, consequently, the public is entitled to review and rely upon it. Goldstein Decl. Exh. C ¶¶ 43-44.

creatively, Defendants' own expert Dr. Goldberg has not been able to identify any reasonable infringement theory under that claim construction (which DPPs' expert Dr. Elder adopted):

[redacted]

Chorush Decl. Exh. C (Goldberg Dep.) at 140:4-18.[13] The reason is simple: [redacted] *Id.* at 137:1-6. [redacted] Elder Decl. Exh. B ¶¶ 29-35; Nalven Decl. Exh. B (Kaplan Reply Report) ¶¶ 15 & 17-18. [redacted]

Because on the undisputed facts there could be no infringement under the properly

[13] [redacted], Defendants could not reasonably hope to prevail under the doctrine of equivalents because that would eviscerate the meaning of the "intimate" limitation, which requires the exclusion of other materials during the co-micronization step. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

construed claims—either literally or under the doctrine of equivalents—each of Defendants' infringement theories in the Capsule Litigation was dismissed involuntarily on summary judgment.

Under these circumstances, no reasonable person of ordinary skill could believe that the "co-micronization" limitation was satisfied with respect to Teva's capsule product [redacted]

Elder Decl. Exh. B ¶¶ 36 & 38.[14]

B. Even Assuming *Arguendo* Defendants' Construction of "Co-Micronization" Were Correct, Defendants' Infringement Theory Was Objectively Baseless.

Defendants' infringement theory was objectively baseless for an independent reason relating to the "co-micronization" limitation. Even under their own overly-broad construction of "co-micronization," Defendants' infringement theory was unreasonable because it required formulations described in the Curtet Patent as non-co-micronized to be co-micronized. The Curtet Patent concept of co-micronization involved mixing fenofibrate and solid surfactant before micronization and specifically touted co-micronization over a process in which the fenofibrate and solid surfactant were mixed after being micronized individually:

> [T]he co-micronization of fenofibrate and a solid surfactant (*i.e.* the micronization of an intimate mixture of fenofibrate and a solid surfactant) makes it possible to improve the bioavailability of the fenofibrate to a

[14] While Purchaser Plaintiffs believe that the reasonableness determination is to be made by the jury, to the extent the Court believes the issue is to be decided as a matter of law, Purchaser Plaintiffs submit that the strong weight of the arguments and evidence supports finding that Defendants' construction was objectively unreasonable.

> significantly greater extent than that which would be achieved. . . by intimately mixing the separately micronized fenofibrate and surfactant.

Chorush Decl. Exh. A at 1:35-43. The Federal Circuit noted this distinction drawn by the Curtet Patent. *Abbott Laboratories*, 323 F.3d at 1330. Having specifically contrasted co-micronized formulations from formulations made by "intimately mixing the separately micronized fenofibrate and surfactant," an argument that the latter (*i.e.*, "intimately mixing the separately micronized fenofibrate and surfactant") constitutes or is equivalent to the former (*i.e.*, co-micronization) is facially unreasonable.

Consistent with this, [redacted]. Chorush Decl. Exh. C (Goldberg Dep.) at 79:18-82:20. [redacted] *Id.* at 89:11-90:1. [redacted]

[redacted]

Chorush Decl. Exh. C (Goldberg Dep.) at 93:14-94:3. [redacted]

The baselessness of Defendants' infringement theory is highlighted by its ramifications for the formulations listed in Table II of the Curtet Patent. Table II of the Curtet Patent compares the dissolution rates for several co-micronized and non-co-micronized formulations. Elder Decl. Exh. B ¶ 43; Chorush Decl. Exh. I (Reginault Dep.) at 123:20-124:13. The formulations in Table II were prepared similarly except that, for the non-co-micronized formulations, the fenofibrate and solid surfactant were micronized separately before mixing. Elder Decl. Exh. B ¶ 43.[15] [redacted]

Id. [redacted]

[15] Curtet Patent inventor Mr. Reginault testified that [redacted] Chorush Decl. Exh. I (Reginault Dep.) at 124:6-13.

[redacted]

Chorush Decl. Exh. E at 11. [redacted]

Elder Decl. Exh. A ¶ 43. A reasonable juror could readily conclude that it was baseless for Defendants to advance an infringement theory that renders the non-co-micronized formulations in the Curtet Patent co-micronized.[17]

[16] [redacted].

[17] Defendants' infringement theory was also unreasonable for the independent reason that the co-precipitation technique on which Defendants relied for infringement was a particle size growth technique rather than a particle size reduction technique. [redacted]

C. No Reasonable Litigant Could Believe the "Solid Surfactant" Limitation Was Satisfied.

Each of the claims in the Curtet Patent requires that a "solid surfactant" participate in the co-micronization. Chorush Decl. Exh. A at 5:6-6:30. Even assuming *arguendo* a reasonable argument—and there is not one—that Teva's capsule product satisfied the "co-micronization" limitation in the Curtet Patent, a genuine issue of material fact exists as to whether Teva's dissolved SLS could reasonably constitute a "solid surfactant."

First, DPPs' expert has opined that Defendants' position was unreasonable. [redacted] Elder Decl. Exh. B ¶ 25. [redacted] Elder Decl. Exh. B ¶ 25. No reasonable person of ordinary skill could believe that the [redacted]

[redacted] Elder Decl. Exh. B ¶ 15; Nalven Decl. Exh. B (Kaplan Reply Report) ¶ 13. [redacted] Elder Decl. Exh. B ¶ 47; Nalven Decl. Exh. B (Kaplan Reply Report) ¶¶ 10-11.

[redacted]

[redacted] *Id.* ¶¶ 36-37.

Second, [redacted]

[redacted]

[redacted] Teva's process employs SLS dissolved in aqueous media (Elder Decl. Exh. B ¶¶ 29-35) [redacted]

[redacted]

[redacted]

Chorush Decl. Exh. F (Colaianni Dep.) at 288:5-289:3. [redacted]

[redacted]

[redacted] Chorush Decl. Exh. C (Goldberg Dep.) at 149:23-150:3. [redacted] *Id.* at 142:14-21.

Third, the Federal Circuit independently reached precisely the same conclusion when it held that

> Dissolved SLS is clearly not a "solid surfactant." Thus even assuming that Novopharm's wet granulation and drying steps results in some reduction in fenofibrate particle size, those steps nonetheless cannot , as a matter of law, constitute co-micronization of an intimate mixture of

> fenofibrate and solid surfactant. To hold otherwise would vitiate that limitation altogether in contravention of the all-elements rule.[18]

Abbott Laboratories, 323 F.3d at 1331 (emphasis added). As DPPs' expert explained, [redacted]

[redacted]

Elder Decl. Exh. B ¶ 27. Given the foregoing, a reasonable juror could adopt Dr. Elder's view and thus a genuine issue of material fact exists as to the reasonableness of Defendants' "solid surfactant" theory.

III. CONCLUSION

Based upon the concurrently-filed Teva and Impax briefs and the arguments and authorities set forth above, Purchaser Plaintiffs respectfully request that this Court deny Defendants' motions for summary judgment relating to sham litigation and *Walker Process* fraud.

Dated: June 2, 2008

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[18] Infringement is therefore precluded not only literally but also under the doctrine of equivalents. *Warner-Jenkinson*, 520 U.S. at 39 n.8.

Inc., Safeway, Inc. and Hy-Vee, Inc., CVS Pharmacy, Inc. Rite Aid Corporation, Rite Aid Hdqtrs. Corp. and American Sales Company, Inc.

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